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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,039	05/20/2004	James T. Dalton	P-5235-US14	7024

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PEARL COHEN ZEDEK LATZER, LLP
1500 BROADWAY 12TH FLOOR
NEW YORK, NY 10036

EXAMINER

KUMAR, SHAILENDRA

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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08/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/849,039	Applicant(s) DALTON ET AL.	
	Examiner SHAILENDRA -. KUMAR	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-95 is/are pending in the application.
- 4a) Of the above claim(s) 21-23, 32-34, 38-51, 65-67, 76-78 and 82-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-20, 24-31, 35-37, 52-64, 68-75 and 79-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1621

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/16/07 has been entered.

Claims 1-9, and 12-95 are pending in this application. Claims 21-23, 32-34, 38-51, 65-67, 76-78 and 82-95 have been withdrawn from the consideration, being drawn to the non elected invention. Claims 10 and 11 have been canceled.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 7/16/07 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 103

3. Claims 1-9, 12-20, 24-31, 35-37, 52-64, 68-75 and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of WO 98/55153 and Tucker et al.

Instant claims are directed to anilide derivatives as metabolites wherein, Q can be among others, F or acetamido.

WO'153 teach structurally similar compounds and composition which are radiolabeled. See pages 6-7, wherein, R7 can be phenyl substituted with amino, F or alkylamido. The difference between the reference and herein claimed compounds and composition is that the reference compounds are radiolabeled as against non radiolabeled compounds claimed herein. Tucker et al are teaching structurally similar

Art Unit: 1621

compounds and composition which are non radiolabeled, see column 1 through column 3.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify WO'153 and obtain non radiolabeled compounds and composition, as taught by Tucker et al, because the latter reference is expressly teaching that structurally similar compounds and composition can be non radiolabeled.

Applicants allege that the examiner has failed to argue all the points raised by the applicants and one of them being with respect to Tucker reference. Applicants argue that Tucker reference is silent with respect to the metabolite part of the claimed compounds. The examiner would like to point out that when the compounds are administered, they will be converted to various metabolites, absent evidence to the contrary. Applicants' arguments with respect to Miller et al is likewise unconvincing because when the compounds are clearly agonist/antagonist as taught by the reference and when administered, they will be in the form of metabolites. Applicants further argue that Tucker makes only S-bridged compounds. The examiner disagrees. See for example, column 9, lines 34-35, wherein O-bridged compounds are expressly made.

Applicants finally point out that neither Tucker nor Miller et al provide any guidance for preparing the metabolites of the compounds of various formulas. The examiner would like to point out the instant specification likewise is merely directed to metabolites and no where there is any process wherein the metabolite can be made in the instant specification. Notwithstanding that, metabolites are inherent when administered to the body.

Double Patenting

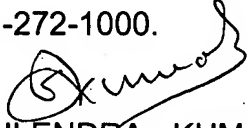
4. Claims 1-9, 12-20, 24-31, 35-37, 52-64, 68-75 and 79-81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-85 of U.S. Patent No. 6,838,484, or over claims 1-10 of U.S. Patent No. 6,569,896, or over claims 1-5 of U. S. Patent No. 6,492,554, all for the reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because various substituents as claimed herein extensively overlap those in the above patents, and one of ordinary skill in the art would have obtained compounds within the generic disclosure of the above patents, because they are structurally so similar to those claimed herein, with the reasonable expectation of achieving a successful composition, absent evidence to the contrary.

Art Unit: 1621

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


SHAILENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
7/30/07